SECTION 3

DEVELOPMENT AND USE OF RISK-BASED CONSUMPTION LIMITS

3.1 OVERVIEW AND SECTION ORGANIZATION

This section describes the derivation and use of the risk-based consumption limit tables provided in Section 4. Consumption limit tables were developed for each of the 25 target analytes listed in Table 1-1 and described in further detail in Volume 1 of this series. This section discusses

- Equations used to calculate the consumption limit tables
- Default values used in developing the consumption limit tables
- Modifications to the consumption limit calculations to allow for different input values and for multiple species consumption and/or multiple contaminant exposure.

Methods for deriving consumption limits for chemical contaminants with carcinogenic and/or noncarcinogenic effects are described. When available data indicate that a target analyte is associated with both carcinogenic and noncarcinogenic health effects, consumption limits based on both types of effects are calculated. In these cases, it is recommended that the toxicological effect resulting in the more conservative consumption limits be used to issue an advisory since resulting limits would be protective of both types of health effects. Methods for calculating consumption limits for a single contaminant in a multiple species diet or for multiple contaminants causing the same chronic health effect endpoints are also discussed. Species-specific consumption limits are calculated in kilograms per day and converted to allowable fish meals in ounces that may be consumed per month. This approach is taken because consumers tend to think of fish consumption in terms of meals rather than in terms of grams or ounces.

Developing fish consumption limits also requires making assumptions about the edible portions of fish because most chemical contaminants are not evenly distributed throughout the fish. The portion of the fish typically eaten may vary by fish species and/or the dietary habits of the fisher population of concern. Most fishers in the United States consume fish fillets. Therefore, it is recommended that contaminant concentrations be measured using skin-on fillets for scaled fish species and skinless fillets for scaleless fish species (e.g., catfish) (see Section 6.1.1.6 in Volume 1 of this series for further discussion of edible fish and shellfish

sample types). However, for populations that ingest whole fish, consumption values corresponding to whole fish contaminant concentrations are more appropriate. Fish consumption patterns are discussed in more detail in Appendix D.

People may be exposed to one or more fish contaminants through sources or pathways other than through consumption of recreationally or subsistence caught fish. These sources include ingestion of contaminated commercially caught fish, other contaminated foods, or contaminated drinking water; inhalation of the contaminant; or dermal contact with contaminated materials including soil and sediment. Caution should be used in setting health safety standards that do not take these other sources into account (see Section 2 for further discussion). Methods for quantifying exposure via sources other than consumption of recreationally or subsistence caught fish are not discussed in detail in this series, although Appendix A provides a list of references and government agencies that may be of assistance in quantifying these other sources of exposure.

3.2 EQUATIONS USED TO DEVELOP RISK-BASED CONSUMPTION LIMITS

Two equations are required to derive meal consumption limits for either carcinogenic or noncarcinogenic health effects. The first equation (3-1 for carcinogenic effects or Equation 3-3 for noncarcinogenic effects) is used to calculate daily consumption limits in units of milligrams of edible fish per kilogram of consumer body weight per day (mg/kg/d); the second equation (3-2) is used to convert daily consumption limits to meal consumption limits over a specified period of time (e.g., 1 month). Toxicological benchmark values for carcinogenic and noncarcinogenic health effects used in the calculation of risk-based consumption limits are summarized in Table 3-1.

3.2.1 Calculation of Consumption Limits for Carcinogenic Effects

To calculate consumption limits for carcinogenic effects, it is necessary to specify an “acceptable” lifetime risk level (ARL). The appropriate risk level for a given population is determined by risk managers; see Volume 3 for further discussion of selection of appropriate risk level. This document presents consumption limits that were calculated using a range of risk levels from 1 in 10,000 (10^{-4}) to 1 in 1 million (10^{-6}). Equations 3-1 and 3-2 were used to calculate risk-based consumption limits for the 14 target analytes with cancer slope factors (see Table 3-1), based on an assumed 70-year exposure. A 70-year lifetime is used in keeping with the default value provided in EPA’s *Exposure Factors Handbook* (U.S. EPA, 1990a). This is a normative value; individuals may actually be exposed for greater or lesser periods of time, depending on their lifespan, consumption habits, and residence location. It should be noted that no populations were identified as being particularly susceptible to the carcinogenic effects of the target analytes. However, readers may wish to calculate consumption limits for specific cohorts (e.g., children, individuals exposed to other carcinogens) based on their interpretation of the toxicological literature and local conditions.

Table 3-1. Risk Values Used in Risk-Based Consumption Limit Tables

Target analyte	Noncarcinogens: Chronic RfD[a] (mg/kg/d)	Carcinogens: q_1*[a] $(mg/kg/d)^{-1}$
Metals		
Arsenic (inorganic)[b]	3×10^{-4}	1.5
Cadmium	1×10^{-3}	NA
Mercury (methylmercury)[c]		
Developmental[d]	1×10^{-4}	NA
Chronic systemic[d]	1×10^{-4}	NA
Selenium[e]	5×10^{-3}	NA
Tributyltin	3×10^{-5}	NA
Organochlorine Pesticides		
Total chlordane (sum of *cis*- and *trans*-chlordane, *cis*- and *trans*-nonachlor, and oxychlordane)[f]	6×10^{-5}	1.3
Total DDT (sum of 4,4'- and 2,4'- isomers of DDT, DDE, and DDD)[g]	5×10^{-4}	0.34
Dicofol[h]	1.2×10^{-3}	0.34
Dieldrin	5×10^{-5}	16
Endosulfan (I and II)[h]	6×10^{-3}	NA
Endrin	3×10^{-4}	NA
Heptachlor epoxide	1.3×10^{-5}	9.1
Hexachlorobenzene	8×10^{-4}	1.6
Lindane (γ-hexachlorocyclohexane; γ-HCH)[i]	3×10^{-4}	1.3
Mirex	2×10^{-4}	1.8
Toxaphene[h,j]	3.6×10^{-4}	1.1
Organophosphate Pesticides		
Chlorpyrifos	3×10^{-3}	NA
Diazinon[h]	9×10^{-5}	NA
Disulfoton	4×10^{-5}	NA
Ethion	5×10^{-4}	NA
Terbufos[h]	1.3×10^{-4}	NA
Chlorophenoxy Herbicides		
Oxyfluorfen	3×10^{-3}	1.28×10^{-1}
PAHs[k]	NA	7.3
PCBs		
Total PCBs (sum of Aroclors)		
Developmental	2×10^{-5} (1254)	
Chronic systemic	2×10^{-5} (1254)	2.0
Dioxins/furans[l]	NA	1.56×10^{5}

NA = Not available in EPA's Integrated Risk Information System (IRIS, 1997).
PAH = Polycyclic aromatic hydrocarbon.
PCB = Polychlorinated biphenyl.
RfD = Oral reference dose (mg/kg/d).
q_1*SF = Cancer slope factor $(mg/kg/d)^{-1}$.

(continued)

Table 3-1 (continued)

[a] Unless otherwise noted, values listed are the most current oral RfDs and q_1* in EPA's IRIS database (IRIS, 1997).

[b] Total inorganic arsenic should be determined.

[c] Because most mercury in fish and shellfish tissue is present primarily as methylmercury (NAS, 1991; Tollefson, 1989) and because of the relatively high cost of analyzing for methylmercury, it is recommended that total mercury be analyzed and the conservative assumption be made that all mercury is present as methylmercury. This approach is deemed to be most protective of human health and most cost-effective.

[d] **Note:** The EPA reevaluated the RfD for methylmercury in 1995, primarily because of concern about evidence that the fetus is at increased risk of adverse neurological effects from exposure to methylmercury (Marsh et al., 1987; Piotrowski and Inskip, 1981; NAS, 1991; WHO, 1976, 1990). On May 1, 1995, IRIS was updated to include an oral RfD of $1x10^{-4}$ mg/kg/d based on developmental neurological effects in human infants. This oral RfD of $1x10^{-4}$ mg/kg/d is considered protective for chronic systemic effects of methylmercury among the general adult population, women of reproductive age, and children. Additional toxicological information on methylmercury is provided in Section 5.

[e] The RfD for selenium is the IRIS (1997) value for selenious acid.

[f] The RfD and q_1* values listed are derived from studies using technical-grade chlordane (purity ~95%) or a 90:10 mixture of chlordane:heptachlor or analytical-grade chlordane (IRIS, 1997). No RfD or SF values are given in IRIS (1997) for the *cis*- and *trans*-chlordane isomers or the major chlordane metabolite, oxychlordane, or for the chlordane impurities *cis*- and *trans*-nonachlor. It is recommended that the total concentration of *cis*- and *trans*-chlordane, *cis*- and *trans*-nonachlor, and oxychlordane be determined.

[g] The RfD value listed is for DDT. The SF value is for DDT or DDE; the SF value for DDD is 0.24. The U.S. EPA Carcinogenicity Assessment Group recommended the use of SF = 0.34 for any combination of DDT, DDE, DDD, and dicofol (Holder, 1986). It is recommended that the total concentration of the 2,4′- and 4,4′-isomers of DDT and its metabolites, DDE and DDD, be determined.

[h] The RfD value listed is from the Office of Pesticide Program's Reference Dose Tracking Report (U.S. EPA, 1996b).

[i] IRIS (1997) has not provided a cancer slope factor for lindane. The q_1* value listed for lindane was calculated from the water quality criteria (0.063 µg/L) (U.S. EPA, 1992i).

[j] The RfD value has been agreed upon by the Office of Pesticide Programs and the Office of Water.

[k] The SF value listed is for benzo[*a*]pyrene. Values for other PAHs are not currently available in IRIS (1997). It is recommended that tissue samples be analyzed for benzo[*a*]pyrene, benz[*a*]anthracene, benzo[*b*]fluoranthene, benzo[*k*]fluoranthene, chrysene, dibenz[*a,h*]anthracene, and indeno*[1,2,3-cd*]pyrene, and that the order-of-magnitude relative potencies given for these PAHs in the EPA provisional guidance for quantitative risk assessment of PAHs (U.S. EPA, 1993d) be used to calculate a potency equivalency concentration (PEC) for each sample (see Section 5.3.2.3 of Volume 1). At this time, EPA's recommendation for risk assessment of PAHs (U.S. EPA 1993d) is considered provisional because quantitative risk assessment data are not available for all PAHs. This approach is under Agency review and will be evaluated as new health effects benchmark values are developed. Therefore, the method provided in this guidance document is subject to change pending results of the Agency's reevaluation.

[l] The SF value listed is for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) (U.S. EPA, 1986e). It is recommended that the 17 2,3,7,8-substituted tetra- through octa-chlorinated dibenzo-p-dioxins and dibenzofurans be determined and a toxicity-weighted total concentration be calculated for each sample, using the revised interim method for estimating Toxicity Equivalency Concentrations (TECs) (Barnes and Bellin, 1989; U.S. EPA, 1991c). If resources are limited, the 2,3,7,8-TCDD and 2,3,7,8-TCDF congeners should be determined at a minimum.

3.2.1.1 Calculation of Daily Consumption Limits—

Equation 3-1 calculates allowable daily consumption of contaminated fish based on a contaminant's carcinogenicity, expressed in terms of kilograms of fish consumed per day:

$$CR_{lim} = \frac{ARL \cdot BW}{q_1 \cdot C_m} \quad (3\text{-}1)$$

where

CR_{lim} = maximum allowable fish consumption rate (kg/d)
ARL = maximum acceptable individual lifetime risk level (unitless)
BW = consumer body weight (kg)
q_1^* = cancer slope factor, usually the upper 95 percent confidence limit on the linear term in the multistage model used by EPA [(mg/kg-d)$^{-1}$], (see Section 2 for a discussion of this value)
C_m = measured concentration of chemical contaminant *m* in a given species of fish (mg/kg).

The calculated daily consumption limit (CR_{lim}) represents the amount of fish (in kilograms) expected to generate a risk no greater than the maximum ARL used, based on a lifetime of daily consumption at that consumption limit.

3.2.1.2 Calculation of Meal Consumption Limits—

Daily consumption limits may be more conveniently expressed as the allowable number of fish meals of a specified meal size that may be consumed over a given time period. The consumption limit is determined in part by the size of the meal consumed. Four meal sizes were used to develop the consumption limit tables for carcinogens in Section 4: 0.114 kg (4 oz), 0.227 kg (8 oz), 0.341 kg (12 oz), and 0.454 kg (16 oz). **Note**: Although all calculations are in units of kilograms, meal sizes are converted to ounces in the tables in Section 4 for ease of risk communication to U.S. consumers. The conversion rate from ounces to kilograms is approximately 1 oz to 0.028 kg, or 1 kg to 35.2 oz. Equations 3-1 and 3-2 can be used to convert daily consumption limits, the number of allowable kilograms per day (calculated using Equation 3-1) to the number of allowable meals per month:

$$CR_{mm} = \frac{CR_{lim} \cdot T_{ap}}{MS} \quad (3\text{-}2)$$

where

Cr_{mm} = maximum allowable fish consumption rate (meals/mo)
Cr_{lim} = maximum allowable fish consumption rate (kg/d)

MS = meal size (kg fish/meal)
T_{ap} = time averaging period (365.25 d/12 mo = 30.44 d/mo).

Equation 3-2 was used to convert daily consumption limits, in kilograms, to meal consumption limits over a given time period (month), as a function of meal size. Monthly consumption limits for carcinogenic effects in adults in the general population were derived for 14 of the 25 target analytes in Section 4.

Other consumption rates, such as meals per week, could also be calculated using this equation by substituting, for example, 7 d/wk for 30.44 d/mo. In using Equation 3-2 in the table calculations in Section 4, the reader should note that 1 month was expressed as 365.25 d/12 mo or 30.44 d/mo.

All meal consumption limits in the tables in Section 4 have been rounded down to the nearest whole number of meals per month, with the exception of the 0.5-meal/mo consumption limits, which are expressed as 6 meals/yr. **Meal consumption limits are rounded down to make them more protective; rounding up would potentially cause them to exceed maximum ARLs for carcinogens.**

3.2.1.3 Input Parameters—

Calculating risk-based consumption limits for carcinogenic effects requires developing appropriate values for the parameters in the equations. The default values used to calculate the consumption limits listed in Section 4 are shown in Table 3-2; a range of values are provided for the measured contaminant concentration in fish tissue (C_m) to represent a broad spectrum of contaminant concentrations. See consumption limit tables in Section 4. Development and modification of these values are discussed in Section 3.3.

EXAMPLE 1: Calculating Monthly Consumption Limits for Carcinogenic Health Endpoints in the General Population for Chlordane

Using Equations 3-1 and 3-2, the monthly meal consumption limits were calculated for the carcinogenic effects of chlordane for adults in the general population as shown in Table 3-3. **Note**: In this section, the monthly consumption limits for chlordane for both carcinogenic and chronic (noncarcinogenic) health effects are used to illustrate various modifications to the monthly consumption limit tables. For developmental effects in women of reproductive age, examples use PCBs as the target analyte.

3.2.2 Calculation of Consumption Limits for Noncarcinogenic Effects

Noncarcinogenic health effects caused by consumption of contaminated fish include systemic effects such as liver, kidney, neurological, muscular, ocular, reproductive, respiratory, circulatory, or other organ toxicities and adverse developmental/reproductive effects from acute and chronic exposure. Risk-based

Table 3-2. Input Parameters for Use in Risk Equations

Equation Parameter[a]	Values
Maximum acceptable risk level (ARL)	10^{-4} (unitless) 10^{-5} (unitless) 10^{-6} (unitless)
Cancer slope factor (q_1*)[b] Reference dose (RfD)	$(mg/kg/d)^{-1}$ mg/kg/d
Consumer body weight (BW)	70 kg (general adult population) 70 kg (women of reproductive age) 14.5 kg (young children < 6 years)
Average fish meal size (MS)	3 oz (0.085 kg) (children only) 4 oz (0.114 kg) 8 oz (0.227 kg) 12 oz (0.341 kg) 16 oz (0.454 kg) (adults only)
Measured contaminant concentration in edible fish and shellfish tissue (C_m)[c]	mg/kg (ppm) varies with local conditions for each chemical contaminant, for each species, and for each size (age) class within a species
Time-averaging period (T_{ap})	30.44 d/mo (monthly limit) 14 d/14-d period (biweekly limit) 10 d/ 10-d period (10-day limit) 7 d/ week (weekly limit)

[a] Selection of the appropriate maximum acceptable risk level, consumer body weight, and average fish meal size are considered risk management decisions. This document provides a range of values for use in risk equations; the risk management decision-making process is discussed in Volume 3 of this guidance series. Selection or calculation of the appropriate cancer slope factor and RfD values may be considered a toxicological, medical, or risk management decision. For information regarding these values, see Sections 2 and 5 of this document and Volume 3.

[b] Most of the q_1*s and RfDs were obtained from EPA's Integrated Risk Information System (IRIS, 1997). The RfDs not listed in IRIS were obtained from EPA's Office of Pesticide Programs. The q_1*s and RfDs used in the risk equations are listed in Table 3-1 and are discussed in Section 5.

[c] Values for contaminant concentrations should be determined from local fish sampling and analysis programs conducted in the waterbody of concern as described in Volume 1.

consumption limit tables for chronic exposure health effects were developed for adults and young children for 23 of the 25 target analytes using RfDs for chronic systemic health effects. Consumption limit tables for women of reproductive age and children were calculated using RfDs for developmental effects for two target analytes—methylmercury and PCBs. Section 5 contains a summary of the overall toxicity of each target analyte. In future revisions of this document, additional consumption limit tables for women of reproductive age and children based on developmental health endpoints will be provided. The equations provided in this

Table 3-3. Monthly Consumption Limits for Carcinogenic Health Endpoints for the General Population—Chlordane

Chemical Concentration in Fish Tissue[a] (mg/kg or ppm)	Recommended Risk—Based Consumption Limit (meals per month)[b]											
	4-oz Meal Size (0.114 kg)			8-oz Meal Size (0.227 kg)			12-oz Meal Size (0.341 kg)			16-oz Meal Size (0.454 kg)		
	ARL			ARL			ARL			ARL		
	10^{-4}	10^{-5}	10^{-6}	10^{-4}	10^{-5}	10^{-6}	10^{-4}	10^{-5}	10^{-6}	10^{-4}	10^{-5}	10^{-6}
<0.0002	>30	>30	>30	>30	>30	>30	>30	>30	>30	>30	>30	>30
0.0002	>30	>30	>30	>30	>30	>30	>30	>30	24	>30	>30	18
0.0004	>30	>30	>30	>30	>30	18	>30	>30	12	>30	>30	9
0.0006	>30	>30	23	>30	>30	12	>30	>30	8	>30	>30	6
0.0008	>30	>30	17	>30	>30	9	>30	>30	6	>30	>30	4
0.001	>30	>30	14	>30	>30	7	>30	>30	4	>30	>30	3
0.002	>30	>30	7	>30	>30	3	>30	24	2	>30	18	1
0.004	>30	>30	3	>30	18	1	>30	12	1	>30	9	6/yr
0.006	>30	23	2	>30	12	1	>30	8	6/yr	>30	6	6/yr
0.008	>30	17	1	>30	9	6/yr	>30	6	6/yr	>30	4	NONE
0.01	>30	14	1	>30	7	6/yr	>30	4	NONE	>30	3	NONE
0.02	>30	7	6/yr	>30	3	NONE	24	2	NONE	18	1	NONE
0.04	>30	3	NONE	18	1	NONE	12	1	NONE	9	6/yr	NONE
0.06	23	2	NONE	12	1	NONE	8	6/yr	NONE	6	6/yr	NONE
0.08	17	1	NONE	9	6/yr	NONE	6	6/yr	NONE	4	NONE	NONE
0.1	14	1	NONE	7	6/yr	NONE	4	NONE	NONE	3	NONE	NONE
0.2	7	6/yr	NONE	3	NONE	NONE	2	NONE	NONE	1	NONE	NONE
0.4	3	NONE	NONE	1	NONE	NONE	1	NONE	NONE	6/yr	NONE	NONE
0.6	2	NONE	NONE	1	NONE	NONE	6/yr	NONE	NONE	6/yr	NONE	NONE
0.8	1	NONE	NONE	6/yr	NONE	NONE	6/yr	NONE	NONE	NONE	NONE	NONE
1	1	NONE	NONE	6/yr	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE
2	6/yr	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE
>2	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE

ARL = Acceptable Risk Level.

NONE = No consumption recommended.

6/yr = Consumption of no more than 6 meals per year is recommended.

> 30 = Although consumption of more than 30 meals/month is allowed, EPA advises limiting consumption to 30 meals in 1 month (1 meal per day).

[a] Shaded values are below detection limit, 1 x 10^{-3} mg/kg.

[b] Instructions for modifying the variables in this table are found in Section 3.3. Consumption limits are calculated based on an adult body weight of 70 kg and using a cancer potency factor of 1.3 per mg/kg/d. References for cancer potency factors are found in Section 5. All values were rounded down to the nearest whole meal size.

section may be used by readers to calculate additional or alternative consumption limits based on their interpretation of toxicological and other literature.

3.2.2.1 Calculation of Daily Consumption Limits—

Equation 3-3 is used to calculate the allowable daily consumption (CR_{lim}) of contaminated fish, based on a contaminant's noncarcinogenic health effects, and is expressed in terms of kilograms of fish per day:

$$CR_{lim} = \frac{RfD \cdot BW}{C_m} \quad (3\text{-}3)$$

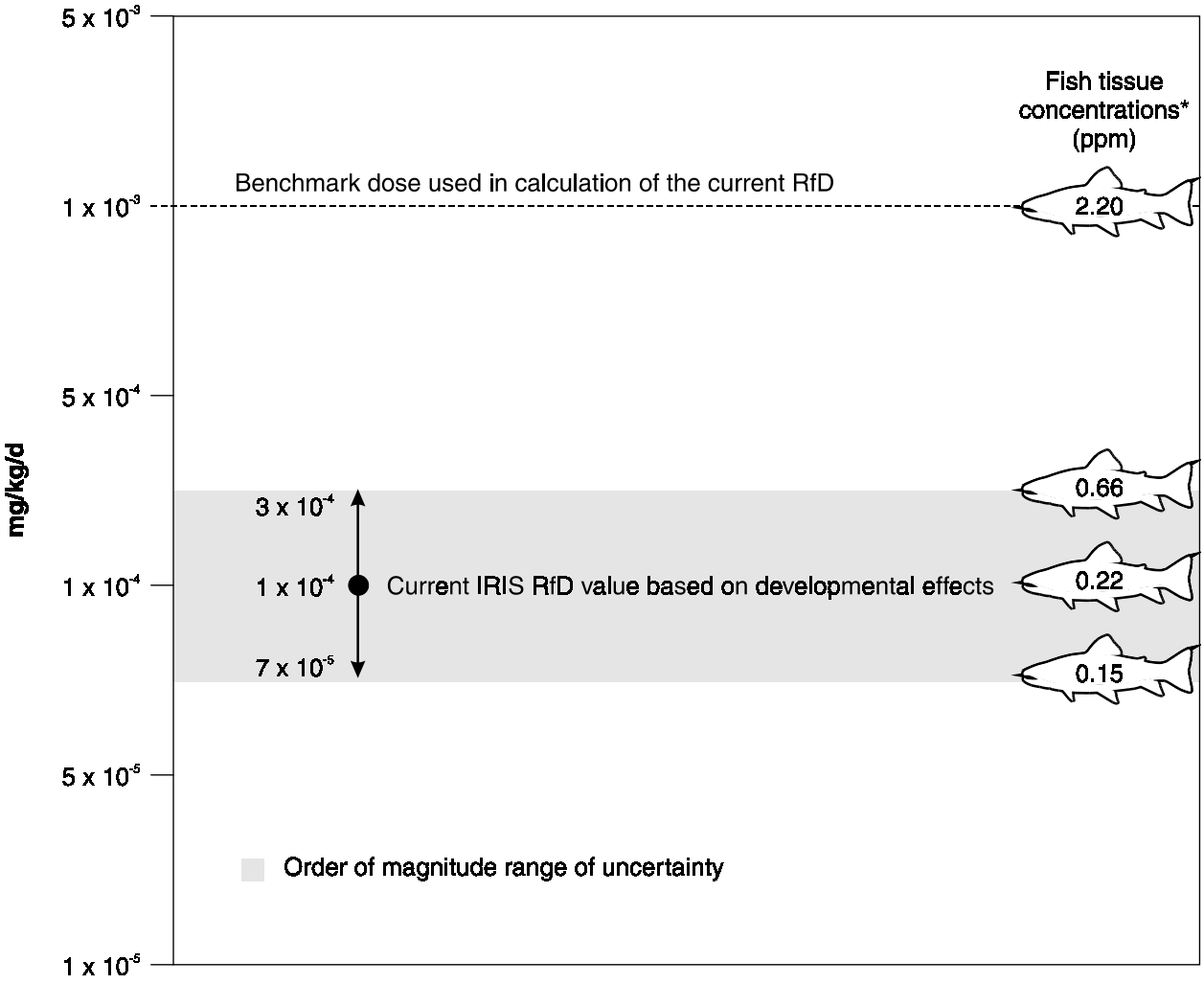
where

CR_{lim} = maximum allowable fish consumption rate (kg/d)
RfE = reference dose (mg/kg/d)
BW = consumer body weight (kg)
C_m = measured concentration of chemical contaminant *m* in a given species of fish (mg/kg).

CR_{lim} represents the maximum lifetime daily consumption rate (in kilograms of fish) that would not be expected to cause adverse noncarcinogenic health effects. Most RfDs are based on chronic exposure studies (or subchronic studies used with an additional uncertainty factor). Because the contaminant concentrations required to produce chronic health effects are generally lower than those causing acute health effects, the use of chronic RfDs in developing consumption limits is expected to also protect consumers against acute health effects. They are designed to protect the most sensitive individuals. This may, however, not be the case for developmental toxicants (see Section 3.2.3).

In 1996, more than 75 percent of all fish consumption advisories issued in the United States were issued wholly or in part as a result of methylmercury contamination. Because the greatest exposure to methylmercury for most individuals is related to consumption of fish and other seafoods, the Office of Water believes a special discussion of methylmercury is warranted. In 1985, EPA published in IRIS an oral RfD for methylmercury of 3×10^{-4} mg/kg/d for chronic systemic effects for the general population. This was based on neurological effects observed in adults in Iraq who ate methylmercury-contaminated grain. Because of concern that the fetus may be at increased risk of adverse neurological effects from exposure to methylmercury, EPA agreed to revise the RfD. In 1993, Volume 1 of this guidance series was published, and EPA's Office of Water recommended use of an interim RfD of 6×10^{-5} mg/kg/d to protect against developmental effects. This value was calculated by dividing the existing RfD of 3×10^{-4} mg/kg/d by a factor of 5. This approach was to be considered interim until such time as the Agency reevaluated new studies on the chronic and developmental effects of methylmercury (U.S. EPA, 1995).

In May 1995, a new RfD of 1×10^{-4} mg/kg/d became available in IRIS. This was based on neurological effects seen in Iraqi children who had been exposed to methylmercury in utero. Data from other human studies also support this RfD. It is acknowledged that the RfD is an estimate with uncertainty spanning perhaps an order of magnitude. Sources of uncertainty include recording and classifying events in the children's lives; uncertainty and variability in the pharmacologic factors that were used in estimating the ingested mercury dose; and the relatively small size of the study population (81 mother-child pairs). Despite these uncertainties, this RfD value is a confident estimate of a level of exposure that can be consumed on a daily basis without expectation of adverse health effects. Figure 3-1 shows the current RfD of 1×10^{-4} mg/kg/d and the upper and lower bounds of the order of magnitude range around this RfD. The shaded area covers the factor



*Calculated assuming consumption of one 8-oz meal (uncooked weight) per week by a 70-kg adult.

Figure 3-1. Current RfD for Methylmercury with Associated Range of Uncertainty and Corresponding Fish Tissue Contamination Levels.

of 3 on either side of the point estimate of the RfD contributing to the total order of magnitude RfD range. As can be seen in Figure 3-1, the former RfD of 3×10^{-4} lies at the top of the range, and the interim value of 7×10^{-5} recommended by the Office of Water for developmental effects lies just below the lower end of the range. The current RfD of 1×10^{-4} mg/kg/d is recommended in this document as being protective against adverse health effects in all population groups—adults, women of reproductive age, and children.

To calculate weekly fish meal consumption limits, Equation 3-3 was modified as follows:

$$C_m = \frac{RfD \times BW}{FR} \qquad (3\text{-}4)$$

Using this equation, one can calculate the level of chemical contamination (C_m) in a given species of fish assuming that a 70-kg adult consumes a maximum of one 8-oz (0.227-kg) meal/wk. As shown in Figure 3-1, the fish tissue concentration of methylmercury, calculated using the current RfD value (1×10^{-4} mg/kg/d or 4.9×10^{-2} mg/wk) and the assumptions as stated above, gives a fish contamination concentration of 0.22 ppm. Using the upper and lower bounds of the RfD range, the corresponding fish tissue concentrations are 0.66 ppm and 0.15 ppm, respectively. One reasonable interpretation of this analysis is that a 70-kg person consuming one meal per week of fish contaminated with a range of 0.15 to 0.66 ppm methylmercury would be exposed to levels within the uncertainty range of the RfD. The RfD is a risk assessment tool that describes an exposure that is expected to be without appreciable risk. The data for methylmercury do not support the prediction of risk for levels of exposure above the RfD. Shown in Figure 3-1 is the benchmark dose, which served as the basis for the methylmercury RfD. The benchmark dose here is the lower bound on an estimated 10 percent risk level for all effects observed in the Iraqi children exposed in utero. In a large population exposed to the benchmark dose of 1×10^{-3} mg/kg/d, some individuals would be expected to show effects.

3.2.2.2 Calculation of Meal Consumption Limits—

Equation 3-2 is used to convert daily consumption limits, in kilograms, to meal consumption limits over given time periods as a function of meal size. Five meal sizes were used to develop the consumption limit tables for noncarcinogenic effects: 3 oz (children only), 4 oz, 8 oz, 12 oz, and 16 oz (adults only). Monthly consumption limits were derived for all target analytes in Section 4 except PAHs and dioxins, for which RfD values are not available. Monthly consumption limits typically pertain to seasonal and subsistence fish consumers (see Section 2.4.5.4). Where appropriate, risk assessors may choose to derive consumption limits based on a shorter time-averaging period such as a 7-day, 10-day, or 14-day period (see Section 3.3.6). These shorter time-averaging periods may be more appropriate to apply to consumption scenarios for recreational fishers who fish primarily during

a 1- to 2-week vacation period. Note that, irrespective of the time-averaging period selected (e.g., 7-day, 10-day, 14-day, monthly), the same chronic systemic RfDs are applicable; the difference is in the averaging periods used in Equation 3-2. Note: This approach does not expressly limit the amount of fish that may be consumed in a given day during the specified time period, so care must be taken to inform consumers of the dangers of eating large amounts of contaminated fish in one meal when certain acute or developmental toxicants are of concern. For example, consuming the monthly consumption limit in 1 day (at one meal) could result in exposures for noncarcinogens that are 30 times the RfD (see Section 2.3 for further discussion).

EXAMPLE 2: Calculating Monthly Consumption Limits for Chronic Systemic Health Endpoints in the General Population for Chlordane

Using Equations 3-3 and 3-2, the monthly meal consumption limits were calculated for the chronic (noncarcinogenic) health effects of chlordane for adults in the general population as shown in Table 3-4. Note: In comparing the consumption limit tables for chlordane based on carcinogenic (Table 3-3) and noncarcinogenic effects for the general population, it is apparent that the carcinogenic endpoint results in a more conservative consumption limit assuming an ARL of 10^{-5} (used to calculate screening values in Volume 1) and equivalent meal sizes and contaminant concentrations in fish tissues. For example, based on a chemical contaminant level in fish tissue of 0.1 ppm, an adult could eat seven 8-oz fish meals assuming an ARL of 10^{-5}. Given the same level of tissue contamination, an adult could eat >30 8-oz meals per month based on noncarcinogenic effects of chlordane. To protect consumers from both the carcinogenic and noncarcinogenic effects of chlordane, a risk assessor may choose to base consumption limits on the more conservative meal sizes derived for carcinogenic effects. In this situation, a risk assessor or risk manager may wish to issue the consumption advisory based on the carcinogenic effects of chlordane, which would be protective of chronic health effects given the above-stated assumptions.

3.2.2.3 Input Parameters—

For noncarcinogenic effects, calculating risk-based consumption limits requires developing appropriate values for similar parameters to those required for carcinogenic effects (see Table 3-2).

3.2.3 Calculation of Consumption Limits for Developmental Effects

This guidance document considers three groups of fishers in deriving risk-based consumption limits: adults in the general population, women of reproductive age, and young children. Both women of reproductive age and young children are known to be at risk from developmental toxicants. There is currently very limited information on the potential reproductive and developmental impact due to

Table 3-4. Monthly Consumption Limits for Chronic Systemic Health Endpoints for the General Population—Chlordane

Chemical Concentration in Fish Tissue[a] (mg/kg or ppm)	Recommended Risk—Based Consumption Limit (meals per month)[b]			
	4-oz Meal Size (0.114 kg)	8-oz Meal Size (0.227 kg)	12-oz Meal Size (0.341 kg)	16-oz Meal Size (0.454 kg)
<0.01	>30	>30	>30	>30
0.01	>30	>30	>30	28
0.02	>30	28	18	14
0.03	>30	18	12	9
0.04	28	14	9	7
0.05	22	11	7	5
0.06	18	9	6	4
0.07	16	8	5	4
0.08	14	7	4	3
0.09	12	6	4	3
0.1	11	5	3	2
0.2	5	2	1	1
0.3	3	1	1	6/yr
0.4	2	1	6/yr	6/yr
0.5	2	1	6/yr	6/yr
0.6	1	6/yr	6/yr	NONE
0.7	1	6/yr	6/yr	NONE
0.8	1	6/yr	NONE	NONE
0.9	1	6/yr	NONE	NONE
1	1	6/yr	NONE	NONE
2	6/yr	NONE	NONE	NONE
>2	NONE	NONE	NONE	NONE

NONE = No consumption recommended.
6/yr = Consumption of no more than 6 meals per year is recommended.
> 30 = Although consumption of more than 30 meals/month is allowed, EPA advises limiting consumption to 30 meals in 1 month (1 meal per day).

[a] Instructions for modifying the variables in this table are found in Section 3.3.
Consumption limits are calculated based on an adult body weight of 70 kg and using RfD = 6×10^{-5} mg/kg/d.
References for RfDs are found in Section 5.
The detection limit is 1×10^{-3} mg/kg.
All values were rounded down to the nearest whole meal size.

[b] Monthly limits are based on the total dose allowable over a 1-month period (based on the RfD).
When this dose is consumed in less than 1 month (e.g., in a few large meals), the daily dose will exceed the RfD (see Section 2.3).

damaged germ cells resulting from exposure of men to developmental toxicants. However, some information on this is provided in Sections 2.3.2.3 and 5. It is well-documented that women exposed to developmental toxicants (e.g., methylmercury and PCBs) may transfer sufficient concentrations of these contaminants in utero or through breast feeding to induce pre- or postnatal developmental damage in their offspring. Information on developmental toxicity has only recently become available for many chemical contaminants. Consequently, the IRIS database, the source of most of the chronic RfDs used to calculate consumption limits, does not contain sufficiently detailed developmental toxicity data for all target analytes. Consumption limits specifically designed to address developmental health effects in women of reproductive age and children have been calculated for methylmercury and PCBs (see Section 4). For methylmercury, the RfD used in this document (1×10^{-4} mg/kg/d) is based on developmental effects (see Section 3.2.2 for a detailed discussion).

For PCBs, the RfD used in this document (2×10^{-5} mg/kg/d) is based on the data available for Aroclor 1254 for ocular and immunological effects in monkeys. The RfD for Aroclor 1016 (7×10^{-5} mg/kg/d) is based on developmental effects in monkeys; however, this value is **less conservative** than the value for Aroclor 1254. Thus, EPA believes that the RfD based on Aroclor 1254 is protective for adults, as well as for developmental effects in women of reproductive age and children, and is using this value for all these groups in this document.

New developmental toxicity data on other target analytes are being reviewed by EPA and will be incorporated in future editions of this document. Readers are referred to Sections 2 and 5, which discuss developmental toxicity. Developmental study data and sources of additional toxicity data are provided in Section 5 so that readers may evaluate available information and make informed decisions concerning developmental toxicity and consumption limits. Exposure limits for developmental and other health endpoints may be calculated by readers, as deemed necessary, using methods described in Section 2.3.2.3.

EXAMPLE 3: Calculating Monthly Consumption Limits for Developmental Endpoints in Women of Reproductive Age for PCBs

In calculating consumption limits for developmental effects in women of reproductive age, Equation 3-3 is used to calculate the allowable daily consumption rate (Cr_{lim}) of contaminated fish (kilograms of fish per day), based on the RfD of 7×10^{-5} mg/kg/d for Aroclor 1016, a bodyweight of 70 kg, and a range of contaminant concentrations in fish tissue. Equation 3-2 is then used to calculate the monthly consumption limits for a specified meal size. This developmental Cr_{lim} represents the maximum lifetime daily consumption rate (kg of fish per day) that would not be expected to cause adverse developmental effects.

(continued)

EXAMPLE 3 (continued)

The use of the RfD for developmental effects of PCBs is derived from the RfD for Aroclor 1016 for which developmental effects have been demonstrated (see Section 5.7 for a detailed discussion of toxicological data on PCBs). When monthly meal consumption limits based on the developmental RfD (Table 3-5) are compared to those for chronic (nondevelopmental) health effects that are based on Aroclor 1254 for the general population (Table 3-6), the monthly meal consumption limits based on nondevelopmental effects are more conservative (restrictive) than those calculated using the developmental RfD. Risk assessors and risk managers may wish to use the more restrictive meal consumption limits developed using the RfD for Aroclor 1254 to be protective of both chronic systemic and developmental health effects based on their population of concern.

3.3 DEFAULT AND ALTERNATIVE VALUES FOR CALCULATING CONSUMPTION LIMITS

The consumption limit tables provided in Section 4 are based on default values for consumer body weights and average meal sizes. These values may not be valid for some recreational and subsistence fisher populations. Readers are encouraged to modify these variables, if necessary, to better fit local conditions relating to consumer body weight, risk level of concern, meal size, new toxicological data, and/or the presence of multiple contaminants. This section describes the default values shown in Tables 3-1 and 3-2 and provides alternative input values and multipliers for use in modifying and/or recalculating the consumption limit tables.

Seven variables are involved in calculating the values in the consumption limit tables (see Equations 3-1 through 3-3):

- Maximum acceptable risk level (ARL)
- Cancer slope factor (q_1*)
- Chronic reference dose (RfD)
- Consumer body weight (BW)
- Fish meal size (MS)
- Contaminant concentration in edible fish tissue (C_m)
- Time-averaging period (e.g., 7-day, 10-day, 14-day, and 30-day period).

Monthly meal consumption limit tables for both the carcinogenic and noncarcinogenic health effects of chlordane are used as examples to illustrate the effects of modifying one or more of the variables listed above. Blank table templates are provided in Appendix G for use in developing new consumption limit tables based on changes in these input parameters.

3.3.1 Maximum Acceptable Risk Level

The consumption limit tables shown in Section 4 for target analytes with carcinogenic effects were calculated for maximum individual ARLs of 10^{-4} to 10^{-6}. Note

Table 3-5. Monthly Consumption Limits for Developmental Health Endpoints for Women of Reproductive Age—PCBs (Aroclor 1016)

Chemical Concentration in Fish Tissue[a] (mg/kg or ppm)	Recommended Risk—Based Consumption Limit (meals per month)[b]			
	4-oz Meal Size (0.114 kg)	8-oz Meal Size (0.227 kg)	12-oz Meal Size (0.341 kg)	16-oz Meal Size (0.454 kg)
<0.02	>30	>30	>30	>30
0.02	>30	>30	21	16
0.03	>30	21	14	10
0.04	>30	16	10	8
0.05	26	13	8	6
0.06	21	10	7	5
0.07	18	9	6	4
0.08	16	8	5	4
0.09	14	7	4	3
0.1	13	6	4	3
0.2	6	3	2	1
0.3	4	2	1	1
0.4	3	1	1	6/yr
0.5	2	1	6/yr	6/yr
0.6	2	1	6/yr	6/yr
0.7	1	6/yr	6/yr	NONE
0.8	1	6/yr	6/yr	NONE
0.9	1	6/yr	NONE	NONE
1	1	6/yr	NONE	NONE
2	6/yr	NONE	NONE	NONE
>2	NONE	NONE	NONE	NONE

NONE = No consumption recommended.
6/yr = Consumption of no more than 6 meals per year is recommended.
> 30 = Although consumption of more than 30 meals/month is allowed, EPA advises limiting consumption to 30 meals in 1 month (1 meal per day).

[a] Instructions for modifying the variables in this table are found in Section 3.3.
Consumption limits are calculated based on an adult body weight of 70 kg and using RfD = 7×10^{-5} mg/kg/d.
References for RfDs are found in Section 5.
Shaded values are below the detection limit, 5×10^{-2} mg/kg.
All values were rounded down to the nearest whole meal size.

[b] Monthly limits are based on the total dose allowable over a 1-month period (based on the RfD).
When this dose is consumed in less than 1 month (e.g., in a few large meals), the daily dose will exceed the RfD (see Section 2.3).

Table 3-6. Monthly Consumption Limits for Chronic Systemic Health Endpoints for the General Population—PCBs (Aroclor 1254)

Chemical Concentration in Fish Tissue[a] (mg/kg or ppm)	Recommended Risk—Based Consumption Limit (meals per month)[b]			
	4-oz Meal Size (0.114 kg)	8-oz Meal Size (0.227 kg)	12-oz Meal Size (0.341 kg)	16-oz Meal Size (0.454 kg)
<0.004	>30	>30	>30	>30
0.004	>30	>30	>30	23
0.005	>30	>30	24	18
0.006	>30	>30	20	15
0.007	>30	26	17	13
0.008	>30	23	15	11
0.009	>30	20	13	10
0.01	>30	18	12	9
0.02	18	9	6	4
0.03	12	6	4	3
0.04	9	4	3	2
0.05	7	3	2	1
0.06	6	3	2	1
0.07	5	2	1	1
0.08	4	2	1	1
0.09	4	2	1	1
0.1	3	1	1	6/yr
0.2	1	6/yr	6/yr	NONE
0.3	1	6/yr	NONE	NONE
0.4	6/yr	NONE	NONE	NONE
0.5	6/yr	NONE	NONE	NONE
0.6	6/yr	NONE	NONE	NONE
0.7	6/yr	NONE	NONE	NONE
>0.7	NONE	NONE	NONE	NONE

NONE = No consumption recommended.
6/yr = Consumption of no more than 6 meals per year is recommended.
> 30 = Although consumption of more than 30 meals/month is allowed, EPA advises limiting consumption to 30 meals in 1 month (1 meal per day).

[a] Instructions for modifying the variables in this table are found in Section 3.3.
Consumption limits are calculated based on an adult body weight of 70 kg and using RfD = 2×10^{-5} mg/kg/d. References for RfDs are found in Section 5.

that the variable ARL appears in the numerator of Equation 3-1, the equation for calculating the daily consumption limit for carcinogens. Because ARL appears in multiples of 10, one may derive new meal consumption limits from the existing tables by multiplying or dividing the existing meal consumption limits by factors of 10, as appropriate. In the same way, changing the ARL by a factor of 10 would cause the same meal consumption limits to be valid for chemical concentrations 10 times higher or 10 times lower than those associated with the original ARL. For example:

- To go from an ARL of 10^{-4} to an ARL of 10^{-3}, shift the meal consumption limit values for the ARL of 10^{-4} to chemical concentrations 10 times **greater** than the original (e.g., if the original meal consumption limit is 12 8-oz meals per month at a contaminant concentration of **0.06 mg/kg** for an ARL of 10^{-4}, then the new meal consumption limit for an ARL of 10^{-3} would be 12 8-oz meals per month at a contaminant concentration of **0.6 mg/kg**. This increases the estimated individual lifetime risk by a factor of 10.
- To go from an ARL of 10^{-6} to an ARL of 10^{-7}, shift the meal consumption values for the ARL of 10^{-6} to chemical concentrations 10 times **lower** than the original (e.g., if the original meal consumption limit is 12 8-oz meals per month at a contaminant concentration of **0.0006** mg/kg for an ARL of 10^{-6}, then the new meal consumption limit for an ARL of 10^{-7} would be 12 8-oz meals per month at a contaminant concentration of **0.00006** mg/kg. This decreases the estimated individual lifetime risk by a factor of 10.

EXAMPLE 4: Modifying the Acceptable Risk Level

The consumption limit table for adults in the general population for the carcinogenic effects of chlordane was taken from Section 4 and modified to include consumption limits for risk levels ranging from 10^{-3} (1 in 1,000) to 10^{-7} (1 in 10,000,000) for an 8-oz meal size as shown in Table 3-7. Consumption limits for other meal sizes (4,12, and 16 oz) have been deleted from the table for clarity. Using this table, the reader can easily see the tenfold effect of modifying the ARL value on the monthly consumption limits for chlordane at specified contaminant concentrations in fish tissues.

3.3.2 Cancer Potencies and Chronic Reference Doses (q_1*s and RfDs)

Table 3-1 contains the risk values used in the development of the consumption limit tables shown in Section 4. All of the q_1*s and RfDs were obtained from EPA databases, primarily from IRIS (1997). Preference was given to IRIS values because these values represent consensus within EPA. When IRIS values were not available, RfDs from other EPA sources were used (see Section 5).

EPA evaluates dose-response data as they become available. Because toxicological data are continually being generated, there may be data available that have not yet been incorporated into the risk values. This is especially relevant for

Table 3-7. Monthly Consumption Limits for Carcinogenic Health Endpoints for the General Population—Chlordane

Chemical Concentration in Fish Tissue[a] (mg/kg or ppm)	Recommended Risk—Based Consumption Limit (meals per month)[b]							
	4-oz	8-oz Meal Size (0.227 kg)					12-oz	16-oz
	ARL	ARL					ARL	ARL
		10^{-3}	10^{-4}	10^{-5}	10^{-6}	10^{-7}		
<0.00004		>30	>30	>30	>30	>30		
0.00004		>30	>30	>30	>30	18		
0.00006		>30	>30	>30	>30	12		
0.00008		>30	>30	>30	>30	9		
0.0001		>30	>30	>30	>30	7		
0.0002		>30	>30	>30	>30	3		
0.0004		>30	>30	>30	18	1		
0.0006		>30	>30	>30	12	1		
0.0008		>30	>30	>30	9	6/yr		
0.001		>30	>30	>30	7	6/yr		
0.002		>30	>30	>30	3	NONE		
0.004		>30	>30	18	1	NONE		
0.006		>30	>30	12	1	NONE		
0.008		>30	>30	9	6/yr	NONE		
0.01		>30	>30	7	6/yr	NONE		
0.02		>30	>30	3	NONE	NONE		
0.04		>30	18	1	NONE	NONE		
0.06		>30	12	1	NONE	NONE		
0.08		>30	9	6/yr	NONE	NONE		
0.1		>30	7	6/yr	NONE	NONE		
0.2		>30	3	NONE	NONE	NONE		
0.4		18	1	NONE	NONE	NONE		
0.6		12	1	NONE	NONE	NONE		
0.8		9	6/yr	NONE	NONE	NONE		
1		7	6/yr	NONE	NONE	NONE		
2		3	NONE	NONE	NONE	NONE		
4		1	NONE	NONE	NONE	NONE		
6		1	NONE	NONE	NONE	NONE		
8		6/yr	NONE	NONE	NONE	NONE		
10		6/yr	NONE	NONE	NONE	NONE		
>15		NONE	NONE	NONE	NONE	NONE		

ARL = Acceptable Risk Level.
NONE = No consumption recommended.
6/yr = Consumption of no more than 6 meals per year is recommended.
> 30 = Although consumption of more than 30 meals/month is allowed, EPA advises limiting consumption to 30 meals in 1 month (1 meal per day).

[a] Shaded values are below detection limit, 1 x 10^{-3} mg/kg.

[b] Instructions for modifying the variables in this table are found in Section 3.3.
Consumption limits are calculated based on an adult body weight of 70 kg and using a cancer potency factor of 1.3 per mg/kg/d.
References for cancer potency factors are found in Section 5.
All values were rounded down to the nearest whole meal size.

developmental toxicity, neurotoxicity, and immunotoxicity data, which are the subject of much current research. To address this, a summary discussion of the toxicity data has been provided in Section 5 for each target analyte; the toxicological profile summaries include a discussion of acute, chronic, developmental, carcinogenic, and genetic toxicity, and special susceptibilities. The summaries contain a brief synopsis of current toxicity data, based on a review of summary documents and databases. Readers are urged to review this information for those target analytes of interest in their geographic areas. A method for estimating acceptable exposure levels from the new data is provided in Section 5; the methods follow the basic dose-response approach recommended by EPA for calculation of RfDs (discussed in Sections 2 and 5). This information is provided to enable readers to use new dose-response data to develop consumption limits if they feel the data warrant such an approach. This may be particularly useful when there are concerns regarding the exposure of children and pregnant and lactating women to developmental contaminants.

3.3.3 Consumer Body Weight (BW)

The consumption limit tables in Section 4 are based on fish consumers of two body weights:

- 70 kg (156 lb), the average body weight of male and female adults in the U.S. population (U.S. EPA, 1990a).
- 14.5 kg (32 lb), the body weight of a young child of 3 to 4 years in the U.S. population (U.S. EPA, 1990a).

As Equation 3-3 shows, consumption limits are linearly related to body weight. That is, the higher the body weight assumed for the population of concern, the higher the consumption limits. EPA's *Exposure Factors Handbook* (U.S. EPA, 1990a) provides additional specific body weight information that can be used to adjust the body weight component of Equation 3-3. The values can also be used to develop a set of multipliers to directly adjust consumption limits for body weight variations.

Table 3-8 provides a range of average body weights (based on age and sex) for the U.S. population and their associated multipliers. Values in bold are those values used in the calculation of the consumption limit tables in Section 4. A **multiplier** is provided for each age group, which represents the number by which the meal consumption limits in the **general adult population** tables may be multiplied to calculate new meal consumption limits using an alternative body weight. The reader should note that, because values in the tables in Section 4 were rounded down to the nearest number of whole meals, minor differences in consumption limits for a specified meal size may occur when the reader calculates the consumption limit directly using Equation 3-2 with the specified body weight found in Table 3-8.

Table 3-8. Average Body Weights and Associated Multipliers

Age Group (yr)[a]	Average Male Body Weight (kg)	Average Female Body Weight (kg)	Average Body Weight for Males and Females Combined (kg)	Multiplier[b]
<3	11.9	11.2	11.6	0.17
3 to 6	17.6	17.1	17.4	0.25
0 to 6	**14.8**	**14.2**	**14.5**	0.21
6 to 9	25.3	24.6	25.0	0.36
9 to 12	35.7	36.2	36.0	0.51
12 to 15	50.5	50.7	50.6	0.72
15 to 18	64.9	57.4	61.2	0.87
18 to 25	73.7	60.6	67.2	0.96
25 to 35	78.7	64.2	71.5	1.0
35 to 45	80.8	67.1	74.0	1.1
45 to 55	81.0	67.9	74.5	1.1
55 to 65	78.8	67.9	73.4	1.0
65 to 75	74.8	66.6	70.7	1.0
18 to 45	—	64	—	0.91
18 to 75	**78.1**	**65.4**	**71.8 (70)[c]**	**1.0**

[a] Numbers in bold represent the default values used to calculate the consumption limit tables.
[b] The body weight multiplier is multiplied by the consumption limits associated with 70-kg adult fish consumers to obtain new consumption limits using the alternative body weight (see Section 3.3.3). The body weight multiplier represents the alternative body weight divided by the adult body weight.
[c] Per recommendations in the *Exposure Factors Handbook*, the body weight value of 71.8 kg for the general adult population was rounded to 70 kg (U.S. EPA, 1990a).

3.3.3.1 Derivation of Multipliers for Body Weight Adjustment—

Body weight multipliers represent the ratio of the alternative body weight to the standard 70-kg adult body weight. Body weight multipliers were calculated as follows:

$$\text{Multiplier}_{BW} = \frac{\text{Alternative Consumer Body Weight}}{\text{General Adult Body Weight}} . \qquad (3\text{-}5)$$

EXAMPLE 5: Calculating Multiplier for Alternative Body Weight

To calculate the multiplier for a 9- to 12-year-old child with an average body weight of 36 kg (see Table 3-8), the equation is:

$$\text{Multiplier}_{BW} = \frac{36\ \text{kg}}{70\ \text{kg}} = 0.51\ \text{(unitless)}$$

where 0.51 represents the ratio between the child body weight (36 kg) and the adult body weight (70 kg). In this document, a body weight of 70 kg was used for all adults, including women of reproductive age, to calculate the consumption limits shown in Section 4. A body weight of 14.5 kg was used in this document to calculate all consumption limits for children.

Readers may wish to modify some or all of these consumption limits using alternative body weight values, based on the health endpoint of concern. For example, if certain developmental toxicants are of concern, exposure of women of reproductive age could be assessed separately. As described in Section 2, a body weight value of 64 kg (143 pounds) can be used to represent the body weight for women of reproductive age, based on the arithmetic mean of the average weights of women of three age groups (18-25, 26-35, and 36-45 years) given in the *Exposure Factors Handbook* (U.S. EPA, 1990a; see Table 3-8). A more protective body weight value to use would be the lower 95th percentile body weight of women age 18 to 25 years (Blindauer, 1994). Readers are encouraged to use local information when available to determine appropriate body weights for calculating exposure limits for populations of concern.

To derive modified consumption limits using alternative values for body weight, multiply the existing consumption limits (in meals per month) found in the tables for the **70-kg adult fisher population** by the multiplier associated with the new body weight:

$$\text{New } CR_{mm} = CR_{mm_{70\text{-kg BW}}} \cdot \text{Multiplier}_{BW} \qquad (3\text{-}6)$$

where

Cr_{mm} = maximum allowable fish consumption rate (meals/mo)
$CR_{mm_{70\text{-kg BW}}}$ = maximum allowable fish consumption rate of a 70-kg fish consumer (meals/mo)
BW = consumer body weight (kg)
Multiplier_{BW} = body weight multiplier (unitless).

If the resultant meal consumption limit is not a whole number, **round down** to the nearest whole number. Rounding up would make the meal consumption limit less

protective. It is also important to note that rounding down the modified CR_{lim} could lead to unnecessarily conservative meal consumption limits, since the original CR_{lim} values for adults have already been rounded down once. Readers may wish to derive more accurate estimates by recalculating meal consumption limits using Equations 3-1 through 3-3 instead of using a multiplier.

EXAMPLE 6: Modifying Consumption Limits for an Alternative Body Weight

To modify Table 3-4 (which shows the monthly consumption limits for chronic systemic health effects in the general adult population from exposure to chlordane) to represent consumption limits for 9- to 12-year-old children weighing an average of 36 kg, multiply each value in the consumption limit table by 0.51:

$$\text{New } CR_{mm} = CR_{mm_{70\text{-kg BW}}} \cdot 0.51$$

Table 3-4 has been modified to represent consumption limits for 36-kg consumers, as shown in Table 3-9. For example, while adults may be able to safely eat nine 8-oz fish meals contaminated with 0.06 mg chlordane/kg fish per month, 9- to 12-year-old children would only be able to safely eat four 8-oz fish meals per month at this same contaminant level ($9 \cdot 0.51 = 4.59$, rounded down to 4) to achieve the same daily contaminant exposure in mg/kg/d.

Scaling to a different body weight may cause the contaminant concentrations of concern to change substantially. Note, for example, that in Table 3-9 all meal consumption limits listed in the original table were effectively halved at any given contaminant concentration to derive the new meal consumption limits for 36-kg consumers. Section 3.3.4 describes the methods used to add meal consumption limits to concentration ranges that fall below the >30 meals per month (“>30”) or above the no consumption (“NONE”) designations in the original table for the 70-kg consumer but no longer do in the modified table. For the purposes of this document, safe fish consumption (represented by “>30” meals in the tables) has been defined as an intake limit of 30 meals per month and no more than one meal per day, for the monthly tables. The definition of no safe fish consumption (represented by “NONE” in the tables) is a health intake limit of less than one meal every 2 months for the monthly tables.

3.3.4 Meal Size

Meal size is defined as the amount of fish (in kilograms) consumed at one meal Four average meal sizes (e.g., 4, 8, 12, and 16 oz) were used to develop consumption limits for the general adult population. Four average meal sizes (e.g., 3, 4, 8, and 12 oz) were also used for children under 4 years of age. **Note**: Although children tend to eat smaller portions than adults, they may consume significantly more fish per unit of body weight. Women of reproductive age (considered separately for methylmercury and PCB consumption limits) were assumed to eat the same amount of fish per meal as other adults.

Table 3-9. Monthly Consumption Limits for Chronic Systemic Health Endpoints for Children—Chlordane

Chemical Concentration in Fish Tissue[a] (mg/kg or ppm)	Recommended Risk—Based Consumption Limit (meals per month)[b]			
	4-oz Meal Size (0.114 kg)	8-oz Meal Size (0.227 kg)	12-oz Meal Size (0.341 kg)	16-oz Meal Size (0.454 kg)
<0.005	>30	>30	>30	>30
0.005	>30	>30	>30	28
0.006	>30	>30	>30	24
0.007	>30	>30	27	20
0.008	>30	>30	24	18
0.009	>30	>30	21	16
0.01	>30	28	19	14
0.02	28	14	9	7
0.03	19	9	6	4
0.04	14	7	4	3
0.05	11	5	3	2
0.06	9	4	3	2
0.07	8	4	2	2
0.08	7	3	2	1
0.09	6	3	2	1
0.1	5	2	1	1
0.2	2	1	6/yr	6/yr
0.3	1	6/yr	6/yr	NONE
0.4	1	6/yr	NONE	NONE
0.5	1	6/yr	NONE	NONE
0.6	6/yr	NONE	NONE	NONE
0.7	6/yr	NONE	NONE	NONE
0.8	6/yr	NONE	NONE	NONE
0.9	6/yr	NONE	NONE	NONE
1	6/yr	NONE	NONE	NONE
1.1	6/yr	NONE	NONE	NONE
>1.1	NONE	NONE	NONE	NONE

NONE = No consumption recommended.
6/yr = Consumption of no more than 6 meals per year is recommended.
> 30 = Although consumption of more than 30 meals/month is allowed, EPA advises limiting consumption to 30 meals in 1 month (1 meal per day).

[a] Instructions for modifying the variables in this table are found in Section 3.3.
Consumption limits are calculated based on a body weight of 36 kg and using RfD = 6×10^{-5} mg/kg/d.
References for RfDs are found in Section 5.
The detection limit is 1×10^{-3} mg/kg.
All values were rounded down to the nearest whole meal size.

[b] Monthly limits are based on the total dose allowable over a 1-month period (based on the RfD).
When this dose is consumed in less than 1 month (e.g., in a few large meals), the daily dose will exceed the RfD (see Section 2.3).

EPA has identified a value of 8 oz (227 g) of cooked fish fillet per 70-kg consumer body weight as an average meal size for adults in the general population and women of reproductive age assuming consumption of noncommercially caught fish only. This meal size, however, does not represent higher end exposures—persons who consume more than the average in a given meal. These larger meal sizes are particularly important to consider in cases where acute or developmental effects from fish contamination are of concern. Therefore, the consumption limit tables in Section 4 provide meal limits based on a range of meal sizes from 4 to 16 oz. For children younger than 4 years of age, EPA has estimated the average fish meal size to be 3 oz (85 g) of cooked fish fillet. Meal sizes of 3 to 12 oz are used in Section 4 for children under 4 years. Development of these values is discussed in Section 2.

Readers may wish to develop fish consumption limits using other meal sizes obtained from data on local fish consumption patterns and/or other fish consumption surveys as appropriate (see Appendix D). Table 3-10 provides alternative meal sizes and their associated multipliers. To obtain modified con-

Table 3-10. Alternative Meal Sizes and Associated Multipliers

Meal Size (oz)[a]	Multiplier[b]
1	8
2	4
3	2.67
4	2.0
5	1.6
6	1.33
7	1.14
8	1.0
9	0.89
10	0.80
11	0.73
12	0.67
13	0.62
14	0.57
15	0.53
16	0.5
24	0.33
32	0.25

[a] Bolded values are those used in the consumption limit tables in Section 4.
[b] The meal size multiplier is multiplied by the consumption limits associated with 8-oz meals to obtain new consumption limits using the alternative meal size.

sumption limits using alternative values for meal size, multiply the existing consumption limits found in the tables for the **8-oz meal size** by the multiplier associated with the new meal size:

$$\text{New } CR_{mm} = CR_{mm_{8\text{-oz MS}}} \cdot \text{Multiplier}_{MS} \quad (3\text{-}7)$$

where variables are as previously defined. If the resultant consumption limit (meals per month) is not a whole number, **round down** to the nearest whole number). For the purposes of this document, safe fish consumption (represented by ">30" meals in the tables) has been defined as an intake limit of 30 meals per month and no more than one meal per day for the monthly tables. The definition of no safe fish consumption (represented by "NONE" in the tables) is a health intake limit of less than one meal every 2 months for the monthly tables.

EXAMPLE 7: Modifying Consumption Limits for an Alternative Meal Size

To modify Table 3-4 to develop values for a 24-oz meal size, multiply the consumption limits for 8-oz meals in the table by one-third, or 0.33:

$$\text{New } CR_{mm} = CR_{mm_{8\text{-oz MS}}} \cdot 0.33 \ .$$

Table 3-4 has been modified as shown in Table 3-11 to represent consumption limits for adults consuming 24-oz (1-1/2-lb or 0.680-kg) fish meals. This shows that, although a 70-kg adult could consume nine 8-oz fish meals contaminated with 0.06 mg chlordane/kg fish, he or she could only consume three 24-oz meals per month ($9 \cdot 1/3 = 3$).

Scaling to a different meal size may cause the concentrations of concern to change substantially. Note that in Table 3-11, meal consumption limits listed in the original table (Table 3-4) were divided by 3 to derive the new consumption limits for 24-oz meals. Sections 3.2.1.2 and 3.2.2.2 describe the methods used to derive meal consumption limits (meals per month) for fish contaminant concentration ranges that fall below the >30 meals per month (>30) or above the no consumption ("NONE") range in the original table for the 8-oz meal size, but no longer do in the modified table.

In addition, if specific meal consumption limits are desired for consumers ages 4 to adult, modifications can be made for both body weight and meal size using the following equation:

$$\text{New } CR_{mm} = CR_{mm_{70\text{ kg BW},8\text{-oz MS}}} \cdot \text{Multiplier}_{BW} \cdot \text{Multiplier}_{MS} \quad (3\text{-}8)$$

where the parameters are as previously defined.

Table 3-11. Monthly Consumption Limits for Chronic Systemic Health Endpoints for the General Population—Chlordane

Chemical Concentration in Fish Tissue[a] (mg/kg or ppm)	Recommended Risk—Based Consumption Limit (meals per month)[b]				
	4-oz Meal Size (0.114 kg)	8-oz Meal Size (0.227 kg)	12-oz Meal Size (0.341 kg)	16-oz Meal Size (0.454 kg)	24-oz Meal Size (0.680 kg)
<0.007	>30	>30	>30	>30	>30
0.007	>30	>30	>30	>30	26
0.008	>30	>30	>30	>30	23
0.009	>30	>30	>30	>30	20
0.01	>30	>30	>30	28	18
0.02	>30	28	18	14	9
0.03	>30	18	12	9	6
0.04	28	14	9	7	4
0.05	22	11	7	5	3
0.06	18	9	6	4	3
0.07	16	8	5	4	2
0.08	14	7	4	3	2
0.09	12	6	4	3	2
0.1	11	5	3	2	1
0.2	5	2	1	1	6/yr
0.3	3	1	1	6/yr	6/yr
0.4	2	1	6/yr	6/yr	NONE
0.5	2	1	6/yr	6/yr	NONE
0.6	1	6/yr	6/yr	NONE	NONE
0.7	1	6/yr	6/yr	NONE	NONE
0.8	1	6/yr	NONE	NONE	NONE
0.9	1	6/yr	NONE	NONE	NONE
1	1	6/yr	NONE	NONE	NONE
2	6/yr	NONE	NONE	NONE	NONE
>2	NONE	NONE	NONE	NONE	NONE

NONE = No consumption recommended.
6/yr = Consumption of no more than 6 meals per year is recommended.
> 30 = Although consumption of more than 30 meals/month is allowed, EPA advises limiting consumption to 30 meals in 1 month (1 meal per day).

[a] Instructions for modifying the variables in this table are found in Section 3.3.
Consumption limits are calculated based on adult body weight of 70 kg and using RfD=$6x10^{-5}$ mg/kg/d.
References for RfDs are found in Section 5.
The detection limit is $1x10^{-3}$ mg/kg.
All values were rounded down to the nearest whole meal size.

[b] Monthly limits are based on the total dose allowable over a 1-month period (based on the RfD). When this dose is consumed in less than 1 month (e.g., in a few large meals), the daily dose will exceed the RfD (see Section 2.3).

EXAMPLE 8: Modifying Consumption Limits for Alternative Body Weight and Meal Size

To modify Table 3-4 for a 3-oz meal size for 3- to 6-year-olds with an average body weight of 17.4 kg, multiply the values for the 8-oz meal size by 0.25 (the body weight multiplier; see Table 3-8) and 2.67 (the meal size multiplier; see Table 3-10):

$$\text{New } CR_{mm} = CR_{mm_{70\text{ kg BW,8-oz MS}}} \cdot 0.25 \cdot 2.67 \ .$$

In this example, the new consumption limits are equivalent to two-thirds (0.67) of the old consumption limits. Table 3-4 has been modified to represent consumption limits for 17.4-kg children consuming 3-oz (0.085 kg) fish meals, as shown in Table 3-12. For clarity, only the meal frequencies for a 3-oz meal size have been calculated. This shows that, although a 70-kg adult could consume nine 8-oz fish meals contaminated with 0.06 mg/kg chlordane (see Table 3-4), a 17.4-kg child could consume only six 3-oz meals per month at the same fish contamination level ($9 \cdot 0.25 \cdot 2.67 = 6$). Again, readers will need to use the methods described in Sections 3.2.1.2 and 3.2.2.2 to add consumption limit values to concentration ranges that fall below 30 meals per month (>30) or above the no consumption ("NONE") range in the original table for adults, but no longer do in the modified table.

3.3.5 Contaminant Concentration in Fish Tissue

Chemical contaminant concentrations in fish tissue are influenced by the specific species and age (size) class of the fish sampled, the chemical properties of the chemical contaminant (e.g., degradation rate, solubility, bioconcentration potential), and the contaminant level in the waterbody. A detailed discussion of selection of target species for use in fish sampling and analysis programs is presented in Section 3 of Volume 1 of this guidance series. In addition, the reader may obtain some indication of the range of contaminant concentrations possible for a specific target analyte in a specific species by reviewing results of regional and national fish sampling programs such as the EPA National Study of Chemical Residues in Fish (U.S. EPA, 1992), the U.S. Fish and Wildlife Service National Contaminant Biomonitoring Program (Lowe et al., 1985; Schmitt et al., 1990), and the National Oceanic and Atmospheric Association (NOAA) Status and Trends Program (NOAA, 1989).

Note: The chemical contaminant concentration in fish tissue values used in calculation of the risk-based consumption limits should be derived from monitoring data obtained from fish sampling and analysis programs and are specific to the waterbody, fish species, and fish size (age) class that were sampled.

Table 3-12. Monthly Consumption Limits for Chronic Systemic Health Endpoints for Children—Chlordane

Chemical Concentration in Fish Tissue[a] (mg/kg or ppm)	Recommended Risk—Based Consumption Limit (meals per month)[b]			
	3-oz Meal Size (0.085 kg)	4-oz Meal Size (0.114 kg)	8-oz Meal Size (0.227 kg)	12-oz Meal Size (0.341 kg)
<0.02	>30			
0.02	18			
0.03	12			
0.04	9			
0.05	7			
0.06	6			
0.07	5			
0.08	4			
0.09	4			
0.1	3			
0.2	1			
0.3	1			
0.4	6/yr			
0.5	6/yr			
0.6	6/yr			
0.7	6/yr			
>0.7	NONE			

NONE = No consumption recommended.
6/yr = Consumption of no more than 6 meals per year is recommended.
> 30 = Although consumption of more than 30 meals/month is allowed, EPA advises limiting consumption to 30 meals in 1 month (1 meal per day).

[a] Instructions for modifying the variables in this table are found in Section 3.3.
Consumption limits are calculated based on a body weight of 17.4 kg and using RfD=$6x10^{-5}$ mg/kg/d.
References for RfDs are found in Section 5.
The detection limit is 1 x 10^{-3} mg/kg.
All values were rounded down to the nearest whole meal size.

[b] Monthly limits are based on the total dose allowable over a 1-month period (based on the RfD). When this dose is consumed in less than 1 month (e.g., in a few large meals), the daily dose will exceed the RfD (see Section 2.3).

3.3.6 Modifying Time-Averaging Period (T_{ap})

Calculated daily consumption limits represent the maximum amount of fish (in kilograms) expected to generate a risk no greater than the maximum ARL used for carcinogens or the maximum amount of fish (in kilograms) that would be expected not to cause adverse noncarcinogenic health effects for noncarcinogens based on a lifetime of daily consumption at that consumption rate. Most fish consumers, however, do not think about consumption in kilograms per day. Therefore, con-

sumption limits may be more conveniently communicated to the fish-consuming public expressed as the allowable number of fish meals of a specified meal size that may be consumed over a given time period.

Monthly consumption limits were derived for all target analytes as shown in Section 4. Monthly consumption limits typically pertain to seasonal and subsistence consumers who consume noncommercially caught fish as a major part of their diets for a greater percentage of the year than recreational fishers. For chemical contaminants with carcinogenic properties, there is no current methodology for evaluating the difference in cancer risks between consuming a large amount of the carcinogenic contaminant over a short period of time and consuming the same amount over the course of a lifetime. Therefore, EPA's current cancer risk assessment guidelines recommend prorating exposure over the lifetime of the exposed individual (U.S. EPA, 1986a). To provide usable and easily understood consumption guidance, the time-averaging period of 1 month was used as the basis for expressing meal consumption limits in Section 4.

For chemical contaminants with noncarcinogenic effects, the situation is slightly different especially when developmental effects are involved. Risk managers may wish to calculate alternative consumption limits for different time intervals that better represent specific populations. For example, 10-day consumption limits are often calculated to apply to fish consumption scenarios for short-term recreational fishers. The 10-day averaging period is a useful period for several reasons (see Section 2.4.3.2). The 10-day averaging period is one of the averaging periods used by the EPA Office of Water in developing health advisories for drinking water, it is also relevant to the short time period often considered critical for exposure to developmental toxicants, and this period corresponds to a typical vacation period.

Using chlordane as an example, 10-day fish consumption limits were calculated for adults in the general population as shown in Example 9.

EXAMPLE 9: Calculating Meal Consumption Limits for a Time-Averaging Period of 10 Days

The monthly meal consumption limits shown in Table 3-4 include a limit for a chlordane contaminant concentration of 0.07 mg/kg fish and a meal size of 4 oz (0.114 kg), based on a chronic systemic RfD of 6×10^{-5} mg/kg/d and a consumer body weight of 70 kg. Using these values for the parameters in Equation 3-3 yields a maximum daily consumption rate of 0.060 kg fish/d:

$$CR_{lim} = \frac{6 \times 10^{-5}\ mg/kg\text{-}d \cdot 70\ kg}{0.07\ mg/kg} = 0.060\ kg\ fish/d.$$

(continued)

EXAMPLE 9 (continued)

Using a meal size of 0.114 kg (4 oz), a consumption rate of 0.060 kg fish/d, and a time-averaging period of 10 days (expressed as 10 days/10-day period), Equation 3-2 yields a meal consumption limit of five meals per 10-day period, as shown in Table 3-13.

$$CR_{mm} = \frac{0.060 \text{ kg/d} \cdot 10 \text{ days/10-day period}}{0.114 \text{ kg/meal}} = 5 \text{ meals/10-day period.}$$

All meal consumption limit modifications may be done in this manner by substituting the appropriate values into Equations 3-1 through 3-3. Note that while meal sizes are given in ounces in the tables in Section 4, they need to be calculated in **kilograms** in Equations 3-1 through 3-3. The conversion rate from ounces to kilograms is approximately 1 oz to 0.028 kg, or 1 kg to 35.2 oz.

3.4 MODIFICATION OF CONSUMPTION LIMITS FOR A SINGLE CONTAMINANT IN A MULTISPECIES DIET

Equations 3-1 and 3-3 may be modified to calculate consumption limits for exposure to a single contaminant through consumption of several different fish species. This section describes the modifications required to do this.

Individuals often eat several species of fish in their diets. Equations 3-1 and 3-3, however, are based on contaminant concentrations in a single species of fish. Where multiple species of contaminated fish are consumed by a single individual, such limits may not be sufficiently protective. If several fish species are contaminated with the same chemical, then doses from each of these species must first be summed across all species eaten, in proportion to the amount of each fish species eaten. This is described by Equation 3-9:

$$C_{tm} = \sum_{j\ 1}^{n} C_{mj} \cdot P_j \qquad (3\text{-}9)$$

where

C_{tm} = total concentration of chemical contaminant *m* in an individual's fish diet (mg/kg)
C_{mj} = concentration of chemical contaminant *m* in species *j* (mg/kg)
P_j = proportion of species *j* in the diet (unitless).

Note: This equation requires that the risk assessor know or be able to estimate the proportion of each fish species in the exposed individual's diet. Equation 3-9 yields the weighted average contaminant concentration across all fish species consumed

Table 3-13. 10-Day Consumption Limits for Chronic Systemic Health Endpoints for the General Population—Chlordane

Chemical Concentration in Fish Tissue[a] (mg/kg or ppm)	Recommended Risk—Based Consumption Limit (meals per 10 days)[b]			
	4-oz Meal Size (0.114 kg)	8-oz Meal Size (0.227 kg)	12-oz Meal Size (0.341 kg)	16-oz Meal Size (0.454 kg)
<0.009	>10	>10	>10	>10
0.009	>10	>10	>10	10
0.01	>10	>10	>10	9
0.02	>10	9	6	4
0.03	>10	6	4	3
0.04	9	4	3	2
0.05	7	3	2	1
0.06	6	3	2	1
0.07	5	2	1	1
0.08	4	2	1	1
0.09	4	2	1	1
0.1	3	1	1	NONE
0.2	1	NONE	NONE	NONE
0.3	1	NONE	NONE	NONE
>0.3	NONE	NONE	NONE	NONE

NONE = No consumption; less than 1 meal per 10 days.

> 10 = Although consumption of more than 10 meals in a 10-day period is allowed, EPA advises limiting consumption to 10 meals in a 10-day period (1 meal per day).

[a] Instructions for modifying the variables in this table are found in Section 3.3.
Consumption limits are calculated based on adult body weight of 70 kg and using RfD=6×10^{-5} mg/kg/d.
References for RfDs are found in Section 5.
The detection limit is 1×10^{-3} mg/kg-d.
All values were rounded down to the nearest whole meal size.

[b] 10-day limits are based on the total dose allowable over a 10-day period (based on the RfD).
When this dose is delivered in less than 10 days (e.g., in a single meal), note that the daily dose will exceed the RfD (see Section 2.3).

(C_{tm}), which then may be used in modified versions of Equations 3-1 to 3-3 to calculate overall and species-specific risk-based consumption limits for carcinogenic and noncarcinogenic effects as shown in Sections 3.4.1 and 3.4.2.

3.4.1 Carcinogenic Effects

The equation to calculate an overall daily consumption limit based on exposure to a single carcinogen in a multiple species diet is very similar to Equation 3-1. However, in place of C_m, which indicates the average chemical contaminant concentration in one species, Equation 3-10 uses the equation for C_{tm}, the weighted average chemical contaminant concentration across all of the species consumed:

$$CR_{lim} = \frac{ARL \cdot BW}{\sum_{j\ 1}^{n} (C_{mj} \cdot P_j) \cdot q_1} \quad (3\text{-}10)$$

where

CR_{lim} = maximum allowable fish consumption rate (kg/d)
ARL = maximum acceptable lifetime risk level (unitless)
BW = consumer body weight (kg)
C_{mj} = concentration of chemical contaminant *m* in fish species *j* (mg/kg)
P_j = proportion of a given species in the diet (unitless)
q_1^* = cancer slope factor, usually the upper 95 percent confidence limit on the linear term in the multistage model used by EPA ([mg/kg/d])$^{-1}$).

The daily consumption limit for each species is then calculated as:

$$CR_j = CR_{lim} \cdot P_j \quad (3\text{-}11)$$

where

Cr_j = consumption rate of fish species *j* (kg/d)
CR_{lim} = maximum allowable fish consumption rate (kg/d)
P_j = proportion of a given species in the diet (unitless).

Meal consumption limits may then be calculated for each species as before, using Equation 3-2 (see Section 3.2), with CR_j substituted for CR_{lim} in the equation. Note that Equation 3-11 may be used before or after Equation 3-2, with the same results.

3.4.2 Noncarcinogenic Effects

For noncarcinogenic effects, the equation to calculate an overall daily consumption limit based on exposure to a single noncarcinogenic chemical in a multiple species diet is similar to Equation 3-3 for a single species. However, in place of C_m, which indicates the chemical contaminant concentration in one species, Equation 3-12 uses the equation for C_{tm}, the weighted average chemical contaminant concentration across all of the species consumed:

$$CR_{lim} = \frac{RfD \cdot BW}{\sum_{j\ 1}^{n} (C_{mj} \cdot P_j)} \quad (3\text{-}12)$$

where the parameters are as defined above. The consumption rate for each species is then calculated using Equation 3-11. Meal consumption limits for each species may then be calculated as before, using Equation 3-2.

EXAMPLE 10: Calculating Consumption Limits for a Single Contaminant in a Multispecies Diet

The combined results from a fish sampling and analysis program and a local fish consumption survey determine that local fishers eat a diet of 30 percent catfish contaminated with 0.006 mg/kg chlordane and 70 percent trout contaminated with 0.008 mg/kg chlordane. The RfD for chlordane reported in IRIS is 0.00006 mg/kg/d (IRIS, 1997). Since chlordane causes both chronic health and carcinogenic effects, consumption limits must be calculated for both health endpoints. The q_1* for chlordane reported in IRIS is 1.3 per $(mg/kg/d)^{-1}$ (IRIS, 1997). The average body weight of an adult is estimated to be 70 kg.

Carcinogenic Effects: Using a risk level of 10^{-5} and the values specified above, Equation 3-5 yields a daily consumption rate of 0.073 kg/d, based on carcinogenic endpoints:

$$CR_{lim} = \frac{10^{-5} \cdot 70\ kg}{(0.006\ mg/kg \cdot 0.3 + 0.008\ mg/kg \cdot 0.7) \cdot 1.3\ per\ mg/kg/d}$$

$$= 0.073\ kg/d\ .$$

Equation 3-2 is then used as before to calculate a monthly meal consumption limit, based on a meal size of 8 oz (0.227 kg):

$$CR_{mm} = \frac{0.073\ kg/d \cdot 30.44\ d/mo}{0.227\ kg/meal} = 9.8 \approx 9\ meals/mo\ .$$

Equation 3-2 yields a meal consumption limit of nine 8-oz meals per month, based on chlordane's carcinogenicity. Equation 3-7 indicates that two 8-oz catfish meals and six 8-oz trout meals per month may be consumed using an acceptable cancer risk level of 10^{-5}.

$$CR_{catfish} = 9\ meals/mo \cdot 0.3 = 2.7 \approx 2\ meals/mo$$

$$CR_{trout} = 9\ meals/mo \cdot 0.7 = 6.3 \approx 6\ meals/mo\ .$$

(continued)

EXAMPLE 10 (continued)

Note: In both cases the meal consumption limits were rounded down. This is a conservative approach. One might also **round up** the number of meals of the species with the **lower** contaminant concentration, and **round down** the number of meals of the species with the **higher** contaminant concentration, so that the total number of fish meals per month equals that found by using Equations 3-6 and 3-2. In this case, since catfish were less contaminated than trout, the consumption limit would be three 8-oz catfish meals and six 8-oz trout meals per month. This approach is based on the proportion of each type of fish eaten. If the actual proportion differs from that used in the equation, the resulting risks may be higher or lower than the targeted risk level (e.g., 10^{-5}).

Noncarcinogenic Effects: Equation 3-8 is used to calculate the daily consumption limit based on chlordane's chronic health effects using the RfD rather than the q_1*.

$$CR_{lim} = \frac{6 \times 10^{-5}\ mg/kg/d \cdot 70\ kg}{0.006\ mg/kg \cdot 0.3 + 0.008\ mg/kg \cdot 0.7} = 0.570\ kg/d\ .$$

As with carcinogenic effects, Equation 3-2 is used to convert the daily consumption limit of 0.570 kg fish to a meal consumption limit:

$$CR_{mm} = \frac{0.570\ kg/d \cdot 30.44\ d/mo}{0.227\ kg/meal} = 76.4 \approx 76\ meals/mo\ .$$

This analysis indicates that 0.57 kg/d is equivalent to 76 8-oz fish meals per month, or over two 8-oz fish meals per day under this mixed-species diet. This is categorized as safe fish consumption (represented by ">30" meals /month) and has been defined as an intake limit of 30 meals per month and no more than one meal per day for the monthly consumption limit tables in Section 4. Thus, based on the above results, risk managers might choose to issue a consumption advisory for adults of two (or three) 8-oz catfish meals and six 8-oz trout meals per month based on chlordane's carcinogenic effects, the more sensitive of the two health endpoints, or elect to base their advisories on noncarcinogenic effects. In addition, they may also review the toxicity data and develop exposure limits based on their interpretation of the toxicity data.

3.5 MODIFICATION OF CONSUMPTION LIMITS FOR MULTIPLE CONTAMINANT EXPOSURES

Equations 3-10 and 3-12 discussed in Section 3.4 can be further modified to develop consumption limits for multiple chemical exposures across single or multiple fish species. Section 2.3.4 provides additional information on exposure to multiple chemical contaminants.

Individuals who ingest chemically contaminated fish may be exposed to a number of different chemicals simultaneously. This could occur when: (1) a single fish species is contaminated with several different chemical contaminants; (2) an individual consumes a mixture of species in his or her diet, each contaminated with a different chemical; or (3) some combination of the above circumstances occurs.

Possible toxic interactions in mixtures of chemicals are usually placed in one of three categories:

- **Antagonistic**—the chemical mixture exhibits less toxicity than the chemicals considered individually
- **Synergistic**—the chemical mixture is more toxic than the sum of the individual toxicities of the chemicals in the mixture
- **Additive**—the toxicity of the chemical mixture is equal to the sum of the toxicities of the individual chemicals in the mixture.

Using available data is especially important in cases where mixtures exhibit synergistic interactions, thereby increasing toxicity. Very little data are available on the toxic interactions between multiple chemicals, however, and no quantitative data on interactions between any of the target analytes considered in this document were located. Some qualitative information is provided in Section 2.3.4.

If all of the chemicals in a mixture induce the same health effect by similar modes of action (e.g., cholinesterase inhibition), contaminants may be assumed to contribute additively to risk (U.S. EPA, 1986d), unless specific data indicate otherwise. Chemicals in a particular class (e.g., organochlorine or organophosphate pesticides) usually have similar mechanisms of toxicity and produce similar effects. Effects of chemicals and chemical groups are discussed in more detail in Section 5 and Appendix C. For mixtures of chemicals that produce similar toxicological endpoints, consumption limits are derived by summing the contaminants from all fish species consumed, as discussed below.

Some chemical mixtures may contain chemicals that produce dissimilar health effects. Methods currently do not exist for combining dissimilar health effects to characterize overall health concerns from chemical mixtures. Instead, the risks from these contaminants need to be characterized and presented separately. It is important to review the overall toxicity of a contaminant in evaluating combined risks because most contaminants are capable of causing multiple effects in numerous organ systems at elevated exposures.

3.5.1 Carcinogenic Effects

Cancer evaluations and q_1*s for most carcinogens are based on animal studies, which are not generally assumed to predict the site of cancer in humans. Consequently, carcinogenic effects are not usually categorized by the cancer site observed in animal studies. Rather, carcinogenic effects are generally assumed to be additive, unless data derived from human studies show them to be otherwise.

Carcinogenic effects for the 14 carcinogens considered in this guidance series are assumed to be additive.

Equation 3-13 can be used to calculate a daily consumption rate for chemical mixtures of carcinogens in single or multiple fish species. It is similar to Equation 3-1, with the summation of all species and all chemicals substituted for C_m in the denominator:

$$CR_{lim} = \frac{ARL \cdot BW}{\sum_{m\ 1}^{x}\left(\sum_{j\ 1}^{n} C_{mj} \cdot P_j\right) \cdot q_{1\ m}} \qquad (3\text{-}13)$$

where

CR_{lim} = maximum allowable fish consumption rate (kg/d)
ARL = maximum acceptable lifetime risk level (unitless)
BW = consumer body weight (kg)
C_{mj} = concentration of chemical contaminant *m* in species *j* (mg/kg)
P_j = proportion of a given species in the diet (unitless)
$q_1^*{}_m$ = cancer slope factor, usually the upper 95 percent confidence limit on the linear term in the multistage model used by EPA ([mg/kg/d]$^{-1}$).

Meal consumption limits for mixtures of carcinogens are then calculated using Equation 3-2. When only one fish species is involved, Equation 3-13 may be simplified to Equation 3-14:

$$CR_{lim} = \frac{ARL \cdot BW}{\sum_{m\ 1}^{x} C_m \cdot q_{1\ m}} \qquad (3\text{-}14)$$

where the variables are as previously defined.

3.5.2 Noncarcinogenic Effects

Equation 3-15 can be used to calculate a daily consumption rate for noncarcinogenic chemical mixtures in single or multiple fish species. It is similar to Equation 3-3, with the summation of all species and all chemicals assumed to act additively substituted for C_m in the denominator and their respective RfDs in the numerator:

$$CR_{lim} = \sum_{m\ 1}^{x}\left(\frac{RfD_m}{\sum_{j\ 1}^{n}(C_{mj} \cdot P_j)}\right) \cdot BW \qquad (3\text{-}15)$$

where the parameters are as previously defined. Meal consumption limits are then calculated using Equation 3-2, as above. Again, when only one fish species is involved, Equation 3-15 can be simplified to Equation 3-16:

$$CR_{lim} = \sum_{m\ 1}^{x} \left(\frac{RfD_m}{C_m} \right) \cdot BW \qquad (3\text{-}16)$$

where the variables are as previously defined. Note that Equations 3-15 and 3-16 may **not** be used for contaminants causing dissimilar noncarcinogenic health effects.

EXAMPLE 11: Calculating Consumption Limits for Multiple Contaminants in a Single Species Diet

A single fish species is contaminated with 0.04 mg/kg chlordane and 0.01 mg/kg heptachlor epoxide. A maximum acceptable risk level of 10^{-5} and an adult body weight of 70 kg are used. Because chlordane and heptachlor epoxide cause both carcinogenic and chronic systemic health effects, both health endpoints must be considered in establishing consumption limits for these chemicals.

Carcinogenic Effects: The q_1^* for chlordane reported in IRIS is 1.3 per (mg/kg/d) (IRIS, 1997). The q_1^* for heptachlor epoxide reported in IRIS is 9.1 per (mg/kg/d) (IRIS, 1997). Equation 3-10 is used to calculate daily consumption rate based on the combined carcinogenic effects of both contaminants:

$$CR_{lim} = \frac{10^{-5} \cdot 70}{(0.04 \cdot 1.3) + (0.01 \cdot 9.1)} = 0.005 \text{ kg/d} .$$

A daily consumption rate of 0.005 kg fish per day is calculated. Using Equation 3-2, this daily consumption rate is converted to a meal consumption limit of one 4-oz meal per month (or six 8-oz meals per year).

Noncarcinogenic Effects: Chlordane and heptachlor are both organochlorine pesticides and cause many similar noncarcinogenic effects. Heptachlor epoxide is a metabolite of the organochlorine pesticide, heptachlor. When heptachlor is released into the environment, it quickly breaks down into heptachlor epoxide. Therefore, the toxicity values used in this document are for heptachlor epoxide, not heptachlor (see Section 5.3.7). Adverse liver effects formed the basis of the RfDs for both chemicals (IRIS, 1997). A combined daily consumption limit based on an RfD of 6×10^{-5} mg/kg/d for chlordane and 1.3×10^{-5} mg/kg/d for heptachlor was calculated using Equation 3-12:

(continued)

EXAMPLE 11 (continued)

$$CR_{lim} = \left(\frac{6 \times 10^{-5} \text{ mg/kg/d}}{0.04 \text{ mg/kg}} + \frac{1.3 \times 10^{-5} \text{ mg/kg/d}}{0.01 \text{ mg/kg}} \right) \cdot 70 \text{ kg} = 0.2 \text{ kg/d} .$$

Equation 3-12 yields a daily consumption rate of 0.2 kg fish/d, at the contaminant concentrations described above. Using Equation 3-2, a meal consumption limit of 26 (4-oz) meals per month is calculated.

Therefore, based on the carcinogenic and chronic systemic consumption limits calculated for combined heptachlor epoxide and chlordane contamination, a risk manager may choose to advise (1) limiting fish consumption to six 8-oz meals per year, based on the combined carcinogenic effects; or (2) limiting fish consumption to 26 4-oz-meals/month, based on noncarcinogenic effects. **In general, EPA advises that the more protective meal consumption limit (in this case, the limit for the carcinogenic effect) serve as the basis for a fish consumption advisory to be protective of both health effects endpoints.** Risk assessors or risk managers may, however, elect to use a third health endpoint (e.g., developmental toxicity), based on their review of the toxicological data for these chemicals.

3.5.3 Species-Specific Consumption Limits in a Multiple Species Diet

Equation 3-11 is used to calculate the risk-based consumption limits for each species in a multiple species diet, for both carcinogenic and noncarcinogenic toxicity where the variables are as defined above. CR_{lim} is calculated using Equations 3-13 or 3-15, for carcinogenic and noncarcinogenic toxicity, respectively. As with the consumption limits for single chemicals, these consumption limits are valid only if the assumed mix of species in the diet is known and if the contaminant concentrations in each species are accurate.

EXAMPLE 12: Calculating Consumption Limits for Multiple Contaminants in a Multispecies Diet

Chlorpyrifos and diazinon both cause cholinesterase inhibition, so are considered together when developing meal consumption limits. The RfD for chlorpyrifos reported in IRIS is 0.003 mg/kg/d (IRIS, 1997), and the RfD for diazinon is 0.00009 mg/kg/d (IRIS, 1997; U.S. EPA, 1993d).

(continued)

EXAMPLE 12 (continued)

A local fish consumption survey reveals that adult fishers consume trout and catfish at a ratio of 70:30, respectively. A fish sampling and analysis program reports chlorpyrifos and diazinon contamination in both species. Trout fillets are contaminated with 4.0 mg/kg chlorpyrifos and 0.3 mg/kg diazinon. Catfish fillets are contaminated with 6.0 mg/kg chlorpyrifos and 0.8 mg/kg diazinon. Given an adult body weight of 70 kg, a risk-based consumption rate of 0.060 kg fish per day is calculated using Equation 3-11:

$$CR_{lim} = \left(\frac{0.003}{(4.0 \cdot 0.7) + (6.0 \cdot 0.3)} + \frac{0.00009}{(0.3 \cdot 0.7) + (0.8 \cdot 0.3)} \right) \cdot 70$$

$$= 0.060 \text{ kg/d} .$$

Using Equation 3-2, a meal consumption limit of eight 8-oz meals per month is derived. **Note**: If chlorpyrifos and diazinon did not cause the same health endpoint, then separate meal consumption limits would have to be calculated for each as described in Section 3.4.2, with the more protective meal consumption limit usually serving as the basis for a fish consumption advisory (see Section 3.5.2).

Equation 3-7 is used to determine meal consumption limits for trout and catfish, based on a diet of 70 percent trout and 30 percent catfish:

$$CR_{trout} = 8 \text{ 8-oz meals/mo} \cdot 0.7 = 5.6 \approx 5 \text{ 8-oz meals/mo} .$$

According to Equation 3-7, an adult may safely consume five 8-oz meals of trout and two 8-oz meals of catfish per month. Again, as mentioned in Section 3.4.2, rounding down both species-specific consumption limits is a conservative approach. One might also **round up** the number of meals of the species with the **lower** contaminant concentration and **round down** the number of meals of the species with the **higher** contaminant concentration, so that the total number of fish meals per month equals that found in Equation 3-11. In this case, since trout were less contaminated than catfish, the species-specific consumption limit would be six 8-oz trout meals and two 8-oz catfish meals per month.

3.6 CHOICE OF CONSUMPTION LIMITS

Where chemicals found in a given species cause dissimilar health effects, dose addition is not often justified scientifically; if dose addition is used in these cases, it must be supported by biological plausibility (U.S. EPA, 1986d). Thus, in most cases where chemicals cause different effects, readers are advised to use the consumption limit for the contaminant that results in the most protective fish consumption advisory for the population of concern. This approach may result in different advisories for each population of concern, since different populations may

have varying health effects of concern (e.g., developmental effects for women of reproductive age and children vs. other chronic effects for adults in the general population). It is important to compare the consumption limits calculated for all chemicals found in a given species and choose the most appropriate consumption limits for each consumer population. This selection may be considered a risk management decision or a medical/toxicological decision.

If local fish sampling and analysis programs and fish consumption surveys determine that consumers are exposed to all four of the contaminants discussed in the above examples (chlordane, heptachlor epoxide, chlorpyrifos, and diazinon), then risk assessors could consider a number of separate fish consumption limits for the chemical mixture:

- A consumption limit could be based on the combined carcinogenic effects of chlordane and heptachlor epoxide, as shown in Example 11.
- A consumption limit could be based on chronic liver damage caused by exposure to the chlordane and heptachlor, as shown in Example 11.
- A consumption limit could be developed for the chronic health effect (cholinesterase inhibition) caused by exposure to both chlorpyrifos and diazinon, as shown in Example 12.
- Consumption limits could be based on new study data reviewed by readers (e.g., xenoestrogenic effects of organochlorines or developmental effects), using the equations provided in this document. Intake limits based on developmental or other toxicological effects can be calculated using the same equations as are used for chronic health endpoints throughout Section 2.

Readers might then base fish consumption advisories for this particular chemical mixture on the most appropriate of the consumption limits for each population of concern. Decisions regarding selection and implementation of consumption limits will be discussed in Volume 3 of this series.

Most fish contaminants have the potential to cause multiple adverse health effects, given sufficiently high exposure levels. Readers are advised to examine the toxicological profile summaries in Section 5 to determine the most appropriate health endpoints on which to base fish consumption limits. Many of the chronic RfDs for organophosphates are currently based on cholinesterase inhibition as the critical health endpoint of concern. However, the EPA's Scientific Advisory Board recently raised concerns about using cholinesterase inhibition as a critical endpoint in the absence of clinical symptoms (U.S. EPA, 1993q). For those who wish to calculate alternative exposure limits for these or other chemical contaminants for use in developing alternative consumption limits, Section 2 provides a summary of current EPA methods for doing so and sources of additional guidance.